UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Mary Karen Moretti,

Plaintiff,

v.

MEMORANDUM OPINION AND ORDER
Civil No. 10-896

Mutual Pharmaceutical Company and Actavis-Elizabeth, LLC,

Defendants.

Daniel J. McGlynn and Terrence J. Donahue, McGlynn, Glisson & Mouton, and Michael K. Johnson and Lucia J. W. McLaren, Goldenberg & Johnson, PLLC, Counsel for Plaintiff.

Michael D. Hutchens and Bradley L. Lindeman, Meagher & Geer, PLLP, Counsel for Defendants.

This matter is before the Court on Defendants' motion for judgment on the pleadings.

I. Background

Plaintiff, a citizen of Nevada, filed this action on March 22, 2010 alleging claims of negligence, misrepresentation, constructive fraud, violations of the Minnesota Deceptive Trade Practices Act, Minnesota False Statement in

Advertising Act and Minnesota Consumer Fraud Act, a violation of the Nevada Deceptive Trade Practices Act, negligent infliction of emotional distress, negligent misrepresentation, and fraud by concealment. Plaintiff's claims are based on allegations that she was prescribed Reglan to treat her gastrointestinal disorders, and from August 2003 through April 10, 2004, Plaintiff ingested metoclopramide, a generic version of Reglan. Defendants are alleged to have tested, developed, manufactured, labeled, marketed, distributed, promoted or sold a generic form of Reglan/metoclopramide, and failed to warn doctors and patients of information which indicated a serious side effect if metoclopramide was taken for an extended period of time. Plaintiff alleges that she took Reglan/metoclopramide for an extended period, and that as a result, she suffered injury.

On March 4, 2011, this action was stayed pending the decision of the United States Supreme Court in Actavis, Inc. v. Demahy and PLIVA, Inc. v. Mensing. On June 23, 2011, the Supreme Court issued its decision, finding that state tort-law claims, based on whether a generic drug manufacturer's alleged failure to adequately warn for metoclopramide, were preempted by federal regulations. PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011).

The stay in this case was then lifted for the limited purpose of allowing the parties to address whether Mensing dictates dismissal of any or all of Plaintiff's claims. It is Defendants' position that Mensing warrants dismissal of all claims on preemption grounds, or in the alternative for failing to state a claim. Plaintiff responds that the Mensing decision addresses only one of the theories of liability asserted in her Complaint, therefore Mensing does not dictate that all claims be dismissed as preempted by federal law.

II. Standard for Judgment on the Pleadings

Judgment on the pleadings is appropriate "where no material issue of fact remains to be resolved and the movant is entitled to judgment as a matter of law." Poehl v. Countrywide Home Loans, Inc., 528 F.3d 1093, 1096 (8th Cir. 2008) (quoting Faibisch v. Univ. of Minn., 304 F.3d 797, 803 (8th Cir. 2002)). The Court must view the facts pleaded by the nonmoving party as true and grant all reasonable inferences in favor of that party. Id.

III. Discussion

A. The Mensing Decision

As previously mentioned, the Mensing decision derives from two cases - Actavis, Inc. v. Demahy was filed in the Eastern District of Louisiana and

Mensing v. Wyeth, Inc. was filed in this District. Mensing involved a plaintiff who ingested Reglan/metoclopramide, and who asserted a number of Minnesota state law-tort claims against the brand name and generic form manufacturers of this drug. The district court granted the generic manufacturer defendants' motion to dismiss on preemption grounds, finding "under the federal regulatory scheme, the labeling for generic drugs must always remain the 'same as' that of the name brand drug and that a generic drug manufacturer cannot unilaterally change its label without prior FDA approval." Id. 562 F. Supp. 2d 1056, 1064-65 (D. Minn. 2008). The court found that any duty under state law to provide heightened warnings on the generic drug would directly conflict with federal regulations. Id. at 1065. The court also rejected the plaintiff's argument that generic drug manufacturers had a duty to propose revised labeling or to provide additional warnings through "Dear Doctor" letters. Id.

The Eighth Circuit reversed the district court's decision that federal law preempted the plaintiff's failure to warn claims against generic manufacturers. Mensing v. Wyeth, Inc., 588 F.3d 603 (8th Cir. 2009). The court determined that it would not be impossible for generic manufacturers to comply with both a heightened state law duty to warn and federal law. Id. at 610-11. The Supreme

Court disagreed, and reversed the decision of the Eighth Circuit, finding that it was impossible for a generic manufacturer to comply with both a heightened state law duty to warn and FDA regulations that require a generic manufacturer to have the same labels as the brand name manufacturers. Mensing, 131 S. Ct. at 2577-78. The Court first rejected the plaintiffs' argument that the "changes-being-effected" (CBE) process under federal regulations allowed generic manufacturers to change their labels when necessary. In so finding, the Court deferred to the FDA's interpretation of its regulations that the CBE process could not be used by generic drug manufacturers to unilaterally change warning labels. Id.

The plaintiffs had also argued that the generic manufacturers could have strengthened their warnings through "Dear Doctor" letters. Id. at 2576. Again, deferring to the FDA's interpretation of its regulations, the Court determined that "Dear Doctor" letters qualify as labeling, therefore generic manufacturers could not send out letters that were inconsistent with or contrary to the drug's approved labeling. Id.

Based on these findings, the Court proceeded with its preemption analysis. The Court first recognized that under the Supremacy Clause, state law must give way to federal law where the laws directly conflict - that is, where "it is

'impossible for a private party to comply with both state and federal requirements.'" Id. at 2577 (quoting Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995)). The Court found that based on the claims before it, and the relevant law, it was impossible for the generic drug manufacturers "to do what state law required of them." Id. The Court also rejected the argument that to prove preemption, the generic manufacturers would have to demonstrate that they sought assistance from the FDA, and that the FDA would not allow compliance with state law. Id. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it. Accepting Mensing and Demahy's argument would render conflict preemption largely meaningless because it would make most conflicts between state and federal law illusory." Id.

On remand, the Eighth Circuit vacated those portions of its opinion that found the failure to warn claims asserted against the generic manufacturers were not preempted. Mensing v. Wyeth, Inc., 658 F.3d 867 (2011). Following the Eighth Circuit's order, the district court determined no issues remained and the case was closed. Mensing v. Wyeth, Inc., Civil No. 07-3919 [Doc. No. 211] (D. Minn. Jan. 20, 2011). Similarly, in the Demahy case, the Fifth Circuit Court of

Appeals vacated the district court's order and remanded the case for entry of judgment in favor of defendant-appellant, Actavis, Inc. Demahy v. Actavis Inc., 650 F.3d 1045 (5th Cir. 2011). Pursuant to the mandate of the Fifth Circuit, the district court entered judgment in favor of the defendants, and dismissed the case with prejudice. Demahy v. Wyeth, Inc., Civil No. 08-3616, 2011 WL 5505399 (E.D. La. Aug. 30, 2011).

B. Plaintiff's Prior Action

Prior to filing the instant complaint, Plaintiff had filed an earlier action against Wyeth, Inc., Schwarz Pharma, Inc., PLIVA, Inc., and Teva Pharmaceuticals, USA, Inc. asserting claims of strict liability, negligence, fraud, among others, arising from injuries she incurred as a result of long-term ingestion of Reglan/metoclopramide. Moretti v. Wyeth, Inc. et al., Civ. No. 07-3920 (DWF/SRN). The Court notes that this case was filed at about the same time as the Mensing case, and that the complaints in the Moretti and Mensing actions are virtually identical. Because Plaintiff Mary Moretti is a citizen of Nevada, however, the first filed Moretti case was transferred to the United States District Court, District of Nevada upon motion of the defendants. Moretti, Civ. No. 07-3920, Memorandum Opinion and Order [Doc. No. 67] (D. Minn. March 17, 2008).

Following the Supreme Court's decision in Mensing, the defendants in the Nevada action moved to dismiss, and the district court granted the motion. Moretti v. Wyeth, Civ. No. 2:08-cv-00396 (JCM/CWH), Minute Order [Doc. No. 282] (D. Nev. Dec. 15, 2011); Id., Transcript of Dec. 15, 2011 Hearing [Doc. No. 283] (Second Lindeman Affidavit, Ex. S.)

In comparing the complaints of the two Moretti actions, it is clear that there are more similarities than differences. The action before this Court is asserted against generic manufacturers of metoclopramide only, while the action transferred to Nevada also included the brand name manufacturer. Both actions, however, assert the same claims based on negligence, fraud and violations of Minnesota statutes, with the exception that this case includes a claim under the Nevada Deceptive Trade Practices Act. Also, the allegations supporting the claims in both actions are substantially similar. The similarities between the Moretti cases and the Mensing case will therefore be taken into consideration in the Court's preemption analysis.

C. Application of Mensing to the Complaint

Plaintiff does not dispute that to the extent her claims are premised on a theory of failure to warn, such claims are preempted by federal regulations, as set

forth in Mensing. Plaintiff argues, however, that she has also alleged that Defendants provided false information regarding metoclopramide, concealed important safety information and knowingly placed an unreasonably dangerous drug into the stream of commerce. Plaintiff alleges that these claims were not addressed by the Court in Mensing, and are thus not preempted by federal law.

In her Complaint, Plaintiff summarized the allegations against Defendants as follows:

> This case involves DEFENDANTS' failure to warn doctors and patients of information within its knowledge or possession or both which indicated the subject Reglan/metoclopramide, when taken for an extended period of time, caused serious, permanent, and debilitating side effects, including tardive dyskinesia.
>
> DEFENDANTS jointly and severally, marketed, manufactured and distributed Reglan/metoclopramide and encouraged the long term use of these drugs, misrepresented the effectiveness of these drugs and concealed the drug's dangerous side effects.

(Complaint ¶¶ 25 and 26.)

Plaintiff further alleged that as a manufacturer of a generic drug, Defendants were required to submit a label that was initially identical to the reference listed drug label. (Id. ¶ 37.) Defendants were also required by federal regulations to ensure the warnings were accurate and adequate, and to conduct

post market safety surveillance and that if in the course of conducting such activities, Defendants discovered information bearing on the risk and/or prevalence of side effects, such discovery must be reported to the medical community. (Id. ¶¶ 38 and 39.) Plaintiff alleged that Defendants failed to investigate the accuracy of the metoclopramide label once they became aware of signals indicating a safety issue and failed to review the relevant medical literature and instead relied on the brand name manufacturer to review such literature. (Id. ¶¶ 39-42.) Plaintiff also alleged that Defendants failed to communicate the true and accurate risks of the severe side effects resulting from the ingestion of metoclopramide, and that Defendants concealed information concerning known serious side effects. (Id. ¶¶ 44, 49-57.)

As discussed above, virtually identical claims were asserted in the Mensing case, and have since been dismissed on preemption grounds. In addition, many courts throughout the country have similarly dismissed claims similar to those asserted herein, pursuant to Mensing decision. See, e.g., Smith v. Wyeth, Inc., 657 F.3d 420 (6th Cir. 2011) (affirming district court's dismissal of claims against generic manufacturers, finding Mensing controlled and that all state tort law claims were preempted); Huck v. Trimark Physicians Group et al., No.

LACV018947 (Iowa Dist. Ct. Jan. 5, 2012) (attached to Defendants' Notice of Supplemental Authority, Ex. A); Moore v. Mylan Inc., __ F. Supp. 2d __, Civil No. 11-CV-030037, 2012 WL 123986 (N.D. Ga. Jan. 5, 2012) (finding that design defect claim based on inadequate warning was preempted); Grinage v. Mylan Pharms., Inc., __ F. Supp. 2d __, 2011 WL 6951962 (D. Md. Dec. 30, 2011) (finding that failure to communicate and defective design claims based on inadequate warnings were preempted); Guarino v. Wyeth LLC, __ F. Supp. 2d __, No. 8:10-cv-2885, 2011 WL 5358709 (M.D. Fla. Nov. 7, 2011) (finding that Mensing rejected failure to communicate claim based on "Dear Doctor" letters).

Plaintiff attempts to differentiate her claims of misbranding/failure to communicate, failure to conduct and report "post-market safety surveillance" on Reglan/metoclopramide and failure to report data regarding the adequacy or accuracy of its warnings from the types of claims addressed in Mensing. The Court is not persuaded by these attempts, however. Despite the different "labels" given these claims, the essence of these claims is that important safety information as to metoclopramide was not disseminated, or made clear, to the public or to the medical community. In other words, Defendants failed to warn of material safety information concerning metoclopramide.

Plaintiff further argues that Defendants could have complied with both state and federal law when it recognized that its labeling was inadequate or inaccurate, by removing its product from the market. Again, the essence of such a claim is the inadequacy or inaccuracy of the labeling, and the Court rejects this additional attempt to recast her failure to warn claims. In addition, in its initial decision, the Eighth Circuit had agreed with this argument, finding that generic drug manufacturers could be held liable for inadequate warnings, because they could have simply stopped selling the drug. Mensing, 588 F.3d at 611. Following remand from the Supreme Court decision, however, the Eighth Circuit vacated this portion of its opinion. Mensing, 658 F.3d at 867. See also Fullington v. PLIVA, Inc., Civ. No. 4:10-CV00236 JLH, 2011 WL 6153608 at *6 (E.D. Ark. Dec. 12, 2011) (noting that argument concerning withdrawal from the market has been overruled).

The Court thus finds that all of Plaintiff's claims asserted herein are barred under the theory of conflict preemption, as set forth in PLIVA, Inc. v. Mensing.

IT IS HEREBY ORDERED that Defendants' Motion for Judgment on the Pleadings [Doc. No. 39] is GRANTED. This action is dismissed with prejudice.

LET JUDGMENT BE ENTERED ACCORDINGLY

Date: February 13, 2012

s/ Michael J. Davis
Michael J. Davis
Chief Judge
United States District Court

Civil No. 10-896